K120605

MAY 18 2012

510(k) Summary of Safety and Effectiveness

SUBMITTER:	Covidien 15 Crosby Drive Bedford, MA 01730
CONTACT PERSON:	James McMahon Manager, Regulatory Affairs 15 Crosby Drive Bedford MA 01730
DATE PREPARED:	February 22, 2012
TRADE/PROPRIETARY NAME:	Permacol™ Surgical Implant
COMMON/USUAL NAME:	Surgical Mesh
CLASSIFICATION NAME:	Surgical Mesh
PREDICATE DEVICE(S):	Permacol™ Surgical Implant (K043366), Primatrix Ag (K100261)
DEVICE DESCRIPTION:	Permacol™ Surgical Implant is a sterile, off-white, moist, tough and flexible, fibrous flat sheet of acellular porcine dermal collagen and its constituent elastin fibers. Presented moist in sterile saline, Permacol™ Surgical Implant is double vacuum packed and heat sealed peel-open aluminum foil (inner) and peel-open polyester/polyethylene (outer) pouches.
INDICATIONS:	Permacol™ Surgical Implant is intended for use as a soft tissue implant to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. It is specifically indicated for the repair of abdominal, inguinal, diaphragmatic, femoral, scrotal, umbilical, incisional,parastomal hernias and abdominal wall defects.
TECHNOLOGICAL CHARACTERISTICS:	Permacol™ Surgical Implant is identical to the predicate device, Permacol™ Surgical Implant, K043366, in terms of its technological characteristics.
MATERIALS:	No material changes are proposed in this submission.
PERFORMANCE DATA:	No new performance data has been included in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 18 2012

Covidien LLC
% Mr. James McMahon
Manager, Regulatory Affairs
15 Crosby Drive
Bedford, Massachusetts 01730

Re: K120605
Trade/Device Name: Permacol™ Surgical Implant
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM, OXK
Dated: May 08, 2012
Received: May 09, 2012

Dear Mr. McMahon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120605

Indications for Use

510(k) Number (if known):

Device Name: Permacol™ Surgical Implant

Indications for Use:

Permacol™ Surgical Implant is intended for use as a soft tissue implant to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. It is specifically indicated for the repair of abdominal, inguinal, diaphragmatic, femoral, scrotal, umbilical, incisional, parastomal hernias, muscle flap reinforcement and abdominal wall defects.

Prescription Use (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)
x		_____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for NXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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